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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,803	09/14/2001	Paul M. Meadows	AB-122U	9492
7590	07/22/2004			
Bryant R Gold Advanced Bionics Corporation 12740 San Fernando Road Sylmar, CA 91342			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/936,803	<b>Applicant(s)</b> MEADOWS ET AL.	
	<b>Examiner</b> George R Evanisko	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the specification is the stimulation pulses: having parameters specified only by data stored in the memory circuits (claim 1); defined only by that at least one stimulation program and data stored within the memory means (claim 9); and defined by parameters specified only by the data stored in that at least one memory circuit (claim 17), in combination with the other elements in the claims. The original specification did not state that the pulses are “only” specified by a program/data stored in the memory circuits and that no other element could specify the pulses. According to MPEP 2173.05(i), “any negative limitation or exclusionary proviso must have basis in the original disclosure” and “the mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 16, “and memory circuits... specified only by data stored in the memory circuits” is vague since it is unclear if these are the same memory circuits used in line 4 (it is suggested to use “the memory circuits... specified”). In addition, “data” is inferentially included. It is suggested to use “the at least one program” from line 5.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5, 7, 9, 10, 12, 13, 15, and 17-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fischell et al (EP 0911061, corresponding US 6144096). The claims only states that the stimulation pulses “have” parameters that are only specified by memory circuits and not that “all” the stimulation parameters are only specified by memory circuits. Since Fischells sensor only changes when the pulses are applied, the stimulation amplitude, frequency, waveform, etc. are “parameters” that are specified “only” by the memory circuits. In addition, Fischell provides a connector, 8, for the electrodes which is the header connector (claims 7 and 15).

In the alternative, Fischell discloses the claimed invention except for the memory circuits specifying/defining the stimulation pulses and parameters based on data and/or programs only in the memory circuits and a header connector on the implantable device to detachably connect the

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electrode array. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the brain stimulation system as taught by Fischell with the memory circuits specifying/defining the stimulation pulses and parameters based on data and/or programs only in the memory circuits, because Applicant has not disclosed that the memory circuits specifying/defining the stimulation pulses and parameters based on data and/or programs only in the memory circuits provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the sensors modifying the stimulation parameters as specified by the data in the memory circuits as taught by Fischell, because it provides a way to turn the pulses on and off and adjust the pulses based on the sensed parameters to allow the patient to receive appropriate therapy and therapy only when it is needed.

Therefore, it would have been an obvious matter of design choice to modify Fischell to obtain the invention as specified in the claim(s).

In addition, for claims 7 and 15, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable pulse generator as taught by Fischell, with a header connector to detachably connect the electrode array since it was known in the art that implantable pulse generators use header connectors to detachably connect the electrode array to the pulse generator to allow the electrode array(s) to be easily implanted or explanted by itself and then connected/uncoupled to the pulse generator to prevent a tangling of wires between themselves and with the pulse generator.

Claims 3, 6, 8, 11, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al.

Fischell discloses the claimed invention except for the diagnostic system or clinician programmer coupled to the hand-held programmer (HHP) through an RF link to communicate with the HHP or through the HHP to the pulse generator (claims 3, 6, 11, and 14) and capacitively coupling the array to the pulse generator (claims 8 and 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the external and implantable system as taught by Fischell, with a diagnostic system or clinician programmer coupled to the hand-held programmer (HHP) through an RF link to communicate with the HHP or through the HHP to the pulse generator and capacitively coupling the array to the pulse generator since it was known in the art that external and implantable systems use the diagnostic system or clinician programmer coupled to the hand-held programmer (HHP) through an RF link to communicate with the HHP or through the HHP to the pulse generator to allow the diagnostic system to quickly, inexpensively, and easily reprogram the HHP or pulse generator without the use of wires that may become tangled and time to connect the wires and since it was known in the art that external and implantable systems use capacitively coupling of the array to the pulse generator to reduce unwanted noise and signals in the array and pulse generator and/or to provide a balanced charge to the electrodes.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. The argument that Fischell does not disclose "leads" with a plurality of electrodes "on" each electrode array is not persuasive since the claims do not state that "leads" are provided and that a plurality of electrodes are "on" each electrode array. The claims only state that an "electrode array" is

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provided having a plurality of electrodes. Fischell shows at least two electrode arrays, each electrode "array" comprising two of the leads and two of the electrodes (such as electrode array 1, leads 17A and 17B and electrodes 15A and 15B, electrode array 2, leads 17C and 17N and electrodes 15C and 15N).

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko  
Primary Examiner  
Art Unit 3762

7/21/4

GRE

July 21, 2004